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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/903,219 | 07/10/2001 | Russell A. Houser | 441742000102 | 9953 |

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EXAMINER

WOO, JULIAN W

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

3731

DATE MAILED: 08/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

EC

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|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 09/903,219 | Applicant(s) HOUSER ET AL. | |
| | Examiner Julian W. Woo | Art Unit 3731 | |
| | | | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 42, 43, 48-50, 52-65 and 68-114 is/are pending in the application.
- 4a) Of the above claim(s) 1-7, 42, 43, 48-50, 52-65, and 68-103 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 104-114 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-7 and 68-71, drawn to a system for implanting a bypass graft, classified in class 606, subclass 194.
 - II. Claims 8-17, drawn to a system for deploying a bypass graft, classified in class 606, subclass 170.
 - III. Claims 20-27, drawn to a process for translumenally deploying a bypass graft, classified in class 606, subclass 99.
 - IV. Claims 42-43, drawn to an anastomotic connector, classified in class 606, subclass 153.
 - V. Claims 48-50 and 52, drawn to a system for deploying and securing at least one end of a bypass graft to a vessel or organ, classified in class 606, subclass 153.
 - VI. Claims 53-63, drawn to a system for securing a bypass graft to at least one vessel, classified in class 623, subclass 1.1.
 - VII. Claims 64 and 65, drawn to a method for creating an anastomosis between a tubular member and a mammalian vessel organ segment, classified in class 128, subclass 898.
 - VIII. Claims 72-103, drawn to an implantable anastomosis bypass graft system and a method of magnetically deploying a tubular graft, classified in class 606, subclass 153.

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IX. Claims 104-114, drawn to an anastomosis connector for connecting a tubular graft to a blood vessel or hollow body organ, classified in class 606, subclass 153.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions III and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process can be practiced by another apparatus.

Inventions VII and V are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process as claimed can be practiced by another apparatus.

Inventions V and IX are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the perforator, dilator, and carrier are tool elements that can be considered apart from a connector. The subcombination has separate utility such as a wound clamp.

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Inventions I, II, IV, VI, VIII, and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. During a telephone conversation with Carol Lasalle, Reg. No. 39,740, on August 14, 2003, a provisional election was made with traverse to prosecute the invention IX, claims 104-114. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-7, 42, 43, 48-50, 52-65, and 68-103 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 110, 111, and 114 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not describe a compressible member comprising a "memory elastic material," nor does the specification describe the expanded profile of the compressible member, which is configured to conform to the interior surface of a vessel or organ.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 106 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not certain whether or not the "tubular graft" is a structural part of the invention.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 104, 107, and 109-112 are rejected under 35 U.S.C. 102(b) as being anticipated by Giannuzzi (4,197,781). With respect to claims 104 and 112, Giannuzzi disclose, in figures 8-11 and in col. 3, line 63 to col. 4, line 58, a connector with at least one, radially deformable compressible member (11) having first and second segments (C and A, D and B), where distal ends of the segments are attached to each other (at 17) and where the compressible member has a first reduced profile and a second expanded profile. With respect to claims 107 and 109, the compressible member is radially self-expanding upon removal of a constraining force. With respect to claims 110 and 111, the compressible member comprises a memory elastic material or a thermoset plastic, such as polypropylene or nylon. Note: The introductory statement of intended use ("for connecting a tubular graft to a blood vessel or hollow organ") has been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable over Giannuzzi's device, which is capable of being used as claimed if one desires to do so.

10. Claims 104, 105, 107, 108, and 110-114 rejected under 35 U.S.C. 102(e) as being anticipated by Huebsch et al. (5,853,422). With respect to claims 104, 105, and 112, Huebsch et al. disclose, in figures 2-5b and in col. 3, line 49 to col. 4, line 51, a

connector with at least one, radially deformable compressible member (10) having first and second segments (22), where distal ends of the segments are attached to each other (at 16) and where the compressible member has a first reduced profile and a second expanded profile. With respect to claims 107 and 108, the compressible member expands upon removal of a catheter (40) that provides a constraining force (e.g., see fig. 5b.) With respect to claims 110 and 111, the compressible member comprises a memory elastic material, such as stainless steel, nickel titanium, or a thermoset plastic. With respect to claim 113, the radially enlarged profile is substantially circular, if the compressible member is viewed along the longitudinal axis. With respect to claim 114, figures 5a and 5b disclose that the compressible member is configured to conform to surfaces of an organ. Note: The introductory statement of intended use ("for connecting a tubular graft to a blood vessel or hollow organ") has been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable over device of Huebsch et al., which is capable of being used as claimed if one desires to do so.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Katsaros et al. (5,630,833) teach a connector with an expandable compressible member.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached at (703) 308-2496.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703) 308-0858. The official FAX number is (703) 872-9302.

A handwritten signature in cursive script that reads "Julian W. Woo".

Julian W. Woo
Primary Examiner

August 18, 2003